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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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02/10/2006

Dieter Dorsch

merck-3121

5899

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7590

04/30/2009

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

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ARLINGTON, VA 22201

EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

04/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No. 10/567,848	Applicant(s) DORSCH ET AL.	
	Examiner REBECCA L. ANDERSON	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-14 is/are rejected.
- 7) ☒ Claim(s) 1-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-28 are currently pending in the instant application. Claims 1-6 and 8-14 are rejected. Claims 1-14 are objected. Claims 15-28 are withdrawn from consideration as being for non-elected subject matter.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 and the further election of the species 4-(4-mitrophenyl)-3-oxomorpholine in the reply filed on 3 March 2009 is acknowledged. The traversal is on the ground(s) that unity of invention exists as Groups I-III relate to intermediate compounds of formula III and are essential precursors or final products. This is not found persuasive because the technical feature of group I is the compound of the formula I and the technical feature of group II and III is formula III. Therefore, the claims lack unity of invention as they are not so linked as to form a single general inventive concept and they lack the same special technical feature.

As per MPEP 803.02, the examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species is not allowable. Therefore, according to MPEP 803.02:

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable **, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. the elected species shall be rejected, and claims to the nonelected species will be held withdrawn from further consideration.

As the elected species has been found not allowable, the Markush-type claims have been rejected and claims to the nonelected invention held withdrawn from further consideration.

Claims 1-14 have been examined to the extent that they are readable on the elected embodiment, the elected species of 4-(4-nitrophenyl)-3-oxomorpholine.

Since the elected embodiment is not allowable, subject matter not embraced by the elected embodiment is therefore withdrawn from further consideration. Claims 15-28 are therefore withdrawn from consideration as being for non-elected subject matter. It has been determined that the entire scope claimed is not patentable.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: Specifically, the specification has multiple references to claim numbers, see for example, pages 17-22, such as page 17 which contains multiple references to claim 15, 16 and 17. It is noted that upon issuance of a patent, the claims may be renumbered and would not correspond to the references to the claims present in the specification. It is suggested that applicant amend the specification to delete the references to the claim numbers without the addition of new matter.

Appropriate correction is required.

Claim Objections

Claims 1-14 are objected to as containing withdrawn subject matter. Claims 1-14 presented drawn solely to the elected embodiment would overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process of preparing the elected embodiment wherein the amine of the formula II has a pKa value of ≤ 3 does not reasonably provide enablement for the preparation of the elected embodiment wherein the amine of the formula II has a pKa value of > 3 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is the preparation of the elected embodiment by reacting formula II with 5-chloro-2,3-dihydro-1,4-dioxin to give the compound of formula III and then formula III is cyclised to give a compound of formula I.

The state of the prior art

The state of the prior art is that the preparation of formula I requires many reaction steps and expensive starting materials, See page 5 of the instant specification.

The predictability or lack thereof in the art

Applicants' have surprisingly found that arylamines, so long as they have a pKa of less than or equal to 3, also react with 2-chlorodioxene to give 2-(2-chloroethoxy)acetamides. This is unexpected since amines, such as ammonia, benzylamine, 8-amino-quinoline or 4-methoxyaniline do not react or react very poorly, see page 6 of the specification.

The amount of direction or guidance present and the presence or absence of working examples

The direction or guidance present is that the compound of formula II must have a pKa of less than or equal to 3 for the reaction to take place, see page 6 of the specification. Additionally the examples present utilize amines of the formula II wherein the pKa is less than or equal to 3.

The breadth of the claims

The breadth of the claims is the preparation of the elected embodiment by reacting formula II with 5-chloro-2,3-dihydro-1,4-dioxin to give the compound of formula III and then formula III is cyclised to give a compound of formula I.

The quantity of experimentation needed and the level of the skill in the art

While the level of skill in the art is high, it would require undue experimentation to prepare the elected embodiment from compounds of the formula II which has a pKa of greater than 3 since it is unexpected that arylamines would react with 2-chlorodioxene to give 2-(2-chloroethoxy)acetamines as long as they have a pKa of less than or equal

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to 3 since amines such as ammonia, benzylamine, or 4-methoxyaniline do not react or react very poorly.

This rejection could be overcome by cancelling claim 7 and importing the limitation of claim 7 into claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

24 April 2009

Rebecca Anderson
Primary Examiner
Art Unit 1626, Group 1620
Technology Center 1600